ArthroCare®

K123240

510(k) Summary

FEB 1 4 2013

ArthroCare® Corporation

SpeedLock® HIP Knotless Fixation Implant

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name:	ArthroCare Corporation
Address	7000 West William Cannon Drive Austin, TX 78735
Contact Person:	Cheryl Frederick Director, Regulatory Affairs Phone: 512-391-5751 Fax: 512-895-1489
Date Prepared:	January 21, 2013

Device Name

Proprietary Name:	SpeedLock® HIP Knotless Fixation Implant
Common Name:	Bone Anchor
Classification Name:	Bone Anchor, Fastener, Fixation, Soft Tissue
Device Class:	Class II
Product Code:	MBI
CFR Section:	21 CFR 888.3040

Predicate Device

This 510(k) relates to a modification to the SpeedLock HIP Knotless Fixation Implant cleared under K120943 (September 21, 2012).

Description

The SpeedLock HIP Knotless Fixation Implant (SpeedLock HIP) is a bone anchor with inserter handle designed for use in arthroscopic and orthopedic procedures. With this anchor, surgical knots are not necessary for the fixation of suture to tissue.

The SpeedLock HIP consists of two primary parts: a 3.4 mm PEEK bone anchor and a disposable anchor inserter which is preloaded with the anchor. The entire product is packaged in a tray with a Tyvek® lid, and the finished product is sterilized by ethylene oxide. Both the anchor and inserter are designed for single use only.

The SpeedLock HIP Knotless Fixation System also includes associated instruments for implanting the anchor into bone.

The design modification that is the subject of this Premarket Notification relates to the internal detachment feature of the SpeedLock HIP anchor. The modification does not alter the overall device characteristics or the manner in which the device is used, and there are no changes to the device's cleared indications for use.

Intended Use/Indications For Use

The SpeedLock HIP Knotless Fixation Implant is indicated for use in fixation of soft tissue to bone in the hip. Examples of such procedures include:

- Hip capsule repair
  - Acetabular labrum reattachment

Non-Clinical Data

The following testing was submitted in support of a determination of substantial equivalence between the predicate and modified devices:

- Design Verification testing to demonstrate conformance with device specifications. This testing included functional testing of all aspects of device performance, use of the device with ancillary devices, and anchor deployment, bone lock and suture lock in a foam bone model.
- Insertion testing in a simulated hard bone substrate.
- Side-by-side comparative testing of the modified and predicate devices, including static and cyclic suture and anchor pull testing, as well as elements of standard verification testing.

The test results demonstrate that the modified SpeedLock HIP Knotless Fixation Implant meets its design, performance, and safety specifications and that it performs substantially equivalently to the predicate SpeedLock HIP Knotless Fixation Implant.

Clinical Data

No clinical or animal data are included in this submission.

Summary

All testing demonstrates that the modified SpeedLock HIP Knotless Fixation Implant performs as intended and has acceptable mechanical properties when used in accordance with its labeling.

Since the modified device's intended use and technological characteristics are the same as those for the previously cleared device, we do not believe that the modification to the SpeedLock HIP Knotless Fixation Implant raises any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2013

ArthroCare Corporation
% Ms. Cheryl Frederick
Director, Regulatory Affairs
7000 West William Cannon Drive
Austin, Texas 78735

Re: K123240
Trade/Device Name: SpeedLock® HIP Knotless Fixation Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: January 21, 2013
Received: January 22, 2013

Dear Ms. Frederick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123240

Indications for Use

510(k) Number (if known): Not yet assigned

Device Name: SpeedLock® HIP Knotless Fixation Implant

Indications for Use:

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  - Acetabular labrum reattachment

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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